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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,007	08/17/2001	Daniel Scherman	03806-0512	2754

7590 04/20/2004

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EXAMINER

SHUKLA, RAM R

ART UNIT PAPER NUMBER

1632

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/931,007

Applicant(s)

SCHERMAN ET AL.

Examiner

Ram R. Shukla

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-82 and 101-112 is/are pending in the application.
- 4a) Of the above claim(s) 8, 29, 33-37, 40, 46-82 and 101-112 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-18, 20-28, 30-32, 38, 39 and 41-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8-27-01 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's response filed 1-21-04 has been entered.
2. Claims 1-82 and 101-112 are pending.
3. Claims 38 and 39 have been amended.
4. ^{19,} Claims 8, ^{19,} 29, 40, 46-82 and 101-112 were withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

It is noted that as noted in the previous office action, claims 33-37 have been withdrawn from further action since the elected species is antisense RNA as the inhibitory transcript and because these claims are drawn to non-elected species. Therefore the withdrawn claims are 8, ^{19,} 29, 33-37, 40, 46-82 and 101-112.

5. Accordingly, claims 1-7, 9-18, 20-28, 30-32, 38, 39 and 41-45 are under consideration.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 1-7, 9-18, 20-28, 30-39 and 41-45 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for reasons of record set forth in the previous office action of 7-23-03. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Response to Arguments

Applicant's arguments filed 1-21-04 have been fully considered but they are not persuasive. Applicants first argue the specification provides cell culture working examples, however claims are directed to in vivo methods which have factors which make the method unpredictable and such factors can not be supported with the in vitro culture examples. While an artisan could use the information from in vitro examples, these examples do not provide how to practice in vivo methods. Next applicants argue that they provide in vivo experiments in specific tissue of mice i.e. skeletal muscle, however, these arguments are not persuasive since the intended use of the claimed method is treatment and based on the discussions of the unpredictability and the undue experimentation associated with in vivo gene therapy the mouse examples do not provide enabling guidance. Applicants have argued that arts such as that of Deonarian, Branch, Jen, Dias articles do not teach that antisense therapy does not work. In fact they say that the method is routinely used. Applicants cite page 263 in Dias article in support of their argument. However, these arguments have been misinterpreted. While it is agreed that the antisense method may have been used in case of a certain gene and a certain antisense targeting the certain gene, the method is not routine. The use of the methods in certain clinical trial does not make it routine. Applicants arguments that examiner has made speculative arguments and challenged presumptively enabled arguments are not persuasive because as noted in the previous office action, USPTO does not have a laboratory and therefore, the examiner cannot go and test applicant's non-enabled invention. The enablement rejection is based on the Wand's factor analysis. Applicants' arguments that one method of using the invention is sufficient to support enablement is not persuasive since that rational is for a composition. In the instant case, it is a method and the method is for gene therapy using antisense transcript and this invention is not enablement in view of the previous office action and discussion above.

In conclusion, the art of antisense therapy is highly unpredictable and the specification has failed to provide sufficient guidance as to how would an artisan

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have dealt with the art recognized issues such as those listed above and therefore it would have required undue experimentation for an artisan to have successfully practiced the claimed invention with a reasonable expectation of success.

8. The 112 second paragraph rejection of claims 38 and 38 has been withdrawn in view of applicants' amendment.

9. No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

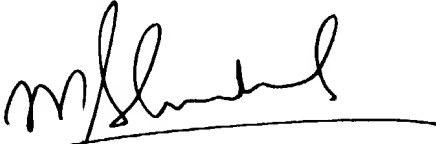
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (571) 272-0735. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The fax phone number for TC 1600 is (703) 703-872-9306. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (571) 272-0548.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ram R. Shukla, Ph.D.
Primary Examiner
Art Unit 1632



**RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER**